

Atty. Dkt. No. 017348-0361

## REMARKS

Claims 1-4 and 14-15 stand rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. The Examiner points to some confusion with the preamble of claim 1 and further indicates a lack of antecedent basis with regard to the terms labeled and magnetized material label. The Examiner also questions the role of the antigen and antibody which have not been defined in the context of the analyte.

In reply to the Examiner's rejections under 35 U.S.C. § 112, applicant has amended the claims in order to remove all of the grounds of rejection set forth in the outstanding Office Action. In particular, the preamble of claim 1 has been amended for clarity to recite "a method of immunoassay with a magnetic field label and a Superconducting Quantum Interference Device". Moreover, applicant has recited that the analyte is prepared by antigen-antibody reaction which has been inserted both into independent claim 1 and independent claim 12. Further, the magnetized magnetic material label which is on the analyte has been clearly set forth as a "magnetized magnetic material labeled analyte". As such, all of applicant's claims are deemed to be in full compliance with the provisions of 35 U.S.C. § 112.

The rejection of claims 1-4 and 12-15 under 35 U.S.C. § 112, first paragraph, is also deemed to be overcome by the changes made and discussed above in connection with the rejection under the second paragraph of § 112. Having clarified the terminology and consistency within applicant's claims, it is submitted that applicant's claims are fully enabling and applicant's specification clearly meets the statutory requirements of 35 U.S.C. § 112, first paragraph.

Claims 1-4 and 12-15 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Weitschies (6,027,946). The Examiner's rejections are respectfully traversed.

It is important to recognize that in accordance with applicant's invention, the magnetic material label which is magnetized by the magnetic field is detected by the SQUID which detects a variation of the strength of the magnetic field which is at a right angle to the magnetic field which is utilized to magnetize the magnetic material label. Thus, as shown in applicant's figure 1, the magnetic field that is utilized to magnetize the magnetic material label is horizontal in the direction of the arrow A. This external magnetic field A is utilized to magnetize the magnetic material label shown by the heavy arrow within the analyte 2.

Atty. Dkt. No. 017348-0361

However, the SQUID has a coil 3 which is positioned to detect the magnetic field which is perpendicular to the horizontal direction, that is, perpendicular to the direction A of the applied magnetic field. Utilizing this arrangement, the SQUID is able to detect the variation of the magnetic field caused by the magnetic material label and free from any influence of the applied magnetic field, thus rendering the SQUID much more sensitive to the changes in magnetic field of the magnetic material label. None of the references cited by the examiner teach nor suggest this highly important limitation of applicant's claims. In particular, applicant's independent claim 1 recites that the magnetic material label which is magnetized by the magnetic field is detected by the SQUID which detects a variation of the strength of a magnetic field which is at a right angle to the magnetic field which magnetizes the magnetic material label. No such teaching is found in any of the references applied by the examiner.

It is pointed out that in order for a reference to be anticipatory under the provisions of 35 U.S.C. § 102, the reference must disclose each and every limitation of the claims. As indicated above, a key limitation of applicant's independent claim is not shown in any of the applied prior art and thus, none of these applied prior art references may be utilized to anticipate applicant's claims. The rejections under 35 U.S.C. § 102 must therefore be withdrawn.

Moreover, applicant notes that the Weitschies reference describes a method in which the magnetic field for magnetization is offloaded while detecting with the SQUID; whereas in applicant's invention, the variation of the magnetic field in the perpendicular direction is detected while the analyte is in the magnetic field which is utilized to magnetize the label. For this reason also, it is submitted that applicant's invention clearly defines over the prior art and is patentable thereover.

The Examiner is requested to acknowledge and approve the formal drawings submitted with the prior amendment mailed October 10, 2002.

Submitted herewith is a three month extension of time and a RCE.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

Atty. Dkt. No. 017348-0361

Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

The application is now believed to be in condition for allowance and an early indication of same is earnestly solicited.

Respectfully submitted,

Date 7-2-03By David A. BlumenthalFOLEY & LARDNER  
Customer Number: 22428

22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5407

Facsimile: (202) 672-5399

David A. Blumenthal  
Attorney for Applicant  
Registration No. 26,257